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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,558	08/26/2003	Robert S. Hamas	94-030576	5528

7590 04/06/2004

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Pittsburgh, PA 15219-1818

EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/649,558

Applicant(s)

HAMAS, ROBERT S.

Examiner

Jackson J Suzette

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 17-20 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/12/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The informal amended changes (*crossed out and initialed writing*) to the specification on page 5 should be modified with a formal amendment. Appropriate correction is required.

Claim Objections

2. Claims 9-10 are objected to because of the following informalities: The informal amended changes (*crossed out and initialed writing*) *should be modified with a formal amendment*. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5, 7-15, 14, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Chaglassian 4,773,909 which discloses the invention as claimed comprising: a first shell/envelope (2) having an exterior surface, and interior surface, and enclosing a lumen; a second shell (4) having an exterior surface, an interior surface, and enclosing a lumen; and one or more fitted shells situated between the exterior surface (3) of the second shell and the interior

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surface of the first shell; wherein the fitted shells are adjacent to each other (see col. 2, lines 40-41); wherein the fitted shells comprise an innermost fitted shell and an outermost fitted shell, wherein the innermost fitted shell is adjacent to the exterior surface of the second shell and the outermost fitted shell is adjacent to the interior surface of the first shell; wherein the fitted shell is generally dome-shaped (col. 2, lines 54-58) and has a diameter measurement and projection measurement; including one or more holes/perforation (12a); made of biocompatible non-porous material; wherein the lumen enclosed by the first shell is filled with the first fluid enveloping at least one of the fitted shell (col. 2, lines 60-67). The intended use recitation/functional language "is able to accommodate a first fluid...is able to accommodate a second fluid...ect." carries no patentable weight in the absence of any distinguishing structure. Chaglassian clearly discloses the structure as claimed and is found to be inherently capable of performing the functions.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6, 13, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaglassian 4,773,909. Chaglassian has been disclosed above noting figures 1-2 however, the inner lumen of the second shell if filled with a gel. It would have been obvious to one having

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ordinary skill in the art at the time the invention was made to exchange the gel into *any* liquid formulation because Chaglassian expressly discloses in column 2, lines 63-65 that *any* other typical liquids which are compatible with the human body may be utilized as long as the consistency and viscosity of the implant material closely simulates the contours and characteristics of the human breast (see col. 3, lines 62-65).

Allowable Subject Matter

7. Claims 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

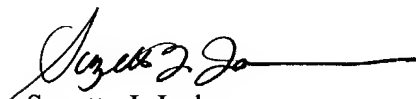
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burg et al. 6,666,893 ; Corbitt, Jr. et al. 6,638,308; Becker 6,183,514 ; Berman 6,146,418 ; Shane 5,358,521 ; Cox Jr. 4,944,750 ; Naficy 4,298,998 ; and Dreschnack et al. 2003/0144734 all show related material.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

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10. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A handwritten signature in black ink, appearing to read 'Suzette J. Jackson', followed by a horizontal line.

Suzette J. Jackson

31 March 2004